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APPLICATION NO. 09/021,560	FILING DATE 02/10/99	FIRST NAMED INVENTOR BARON	M	ATTORNEY DOCKET NO. 1572/111
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HM22/0619

KAUFMAN EXAMINER

ABEUNA	PAPER NUMBER
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06/19/01

24

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.

09/021,660

Applicant(s)

BARON ET AL.

Examiner

Claire M. Kaufman

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 June 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 57-81.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other:

Continuation of 2. NOTE: The amendment if entered would raise many new issues requiring further consideration. For example, new claim 81 would raise new issues under 35 USC 112, first paragraph; Applicants ask for cancellation of claims 76-81, but add claims 80 and 81 as new claims and have dependent claims; there is confusion between claims 80 and 84. The specification would remain objected to because abstract must be on separate page.

Continuation of 3. Applicants' reply would overcome the following rejection(s): the rejection under 35 USC 112, second paragraph, of claims 57, 61 and 62. Cancellation of claims 76-81 would moot all rejections of those claims.

Continuation of 5. does NOT place the application in condition for allowance because: Claims would remain rejected under 35 USC 112, first paragraph, for lack of written description because such a rejection is not limited to product claims. Method claims are rightly rejected if there is not adequate written description of the products required to practice the method. Clarification for argument bridging pages 11-12 of response is as follows: claims encompass non-vertebrate hedgehog proteins. While mouse Shh might have some function in *Drosophila*, what function if any *Drosophila* hh would have in a much more complex organism, such as a mouse, is unpredictable. The issue of a single means claim is applicable to the instant method claims because the products required by the methods are being claimed by what they do not what they are. Applicants argue that a functionally equivalent compound would work in the instant methods and Examiner has not said why they wouldn't. One cannot use what one cannot make. For the reasons in the previous Office action, it would require undue experimentation to make a commensurate number of compounds that have the necessary function for the claimed invention. Applicants argue that that the Examiner has not provided evidence that TPO meets the requirements of a function equivalent of hh. As stated in the previous Office action, TPO has the required function (i.e., stimulating a population of undifferentiated mesodermally-derived cells to undergo hematopoiesis); therefore, it is functional equivalent.

CLAIRE KAUFMAN
PATENT EXAMINER

Claire M. Kaufman
6/15/01